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Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?

PRINCIPAL INVESTIGATOR:

Edna B. Foa

CONTRACTING ORGANIZATION:

The Trustees of the University of Pennsylvania, Philadelphia, PA 191094

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14. ABSTRACT

The dramatic increase in the number of active duty soldiers identified with PTSD has produced an urgent need to train military mental health providers in how to effectively deliver short-term, efficacious, evidence-based treatments (EBTs) for PTSD. Prolonged exposure (PE) has gained the most empirical evidence for its efficacy and has many characteristics that render it an excellent candidate for dissemination: it is effective with a wide range of PTSD sufferers, it is relatively easy to learn and deliver, and it is preferred by patients over some other treatments. Research indicates that case consultation after participation in a workshop plays an important role in training mental health professionals to successfully implementing EBTs. However, consultation requires a greater investment of resources than a one-time workshop. Thus, it is critical to determine whether consultation increases the success of disseminating and implementing long-term sustainability of PE services.

15. SUBJECT TERMS- none listed

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INTRODUCTION

Prolonged exposure (PE) therapy for PTSD has many characteristics that render it an excellent candidate for dissemination: it is effective for PTSD associated with a wide range of trauma types, it is efficacious with individuals who have PTSD and a variety of comorbidities (e.g., depression, psychosis, self-injury, anger, mild and moderate TBI; see Cahill, Rauch, Hembree, & Foa, 2003; Hagenaars, van Minnen, & Hoogduin, 2010; Harned, Korslund, & Linehan, 2014; Hembree, Cahill, & Foa, 2004; Sripada et al., 2013; van den Berg et al., 2015), it is relatively easy to learn and deliver (e.g., Foa et al., 2005) , and it is preferred by patients over some other treatments such as medication (Chen, Keller, Zoellner, & Feeny, 2013). Research indicates that case consultation after participation in a workshop increases the self-confidence of the therapist in PE delivery (Karlin et al., 2010), which in turn increases the number of patients that they treat with PE (Rosen et al., 2015). However, consultation requires a greater investment of resources than a workshop. Thus, it is critical to determine whether consultation increases the success of disseminating and implementing PE services in routine clinical care. This study will examine the relative success of disseminating and implementing EBTs for PTSD in the Army in two PE training models: Standard PE training (workshop only) and Extended PE training (workshop plus consultation). The study will recruit approximately 35 mental health therapists in each of three medium- to large-sized domestic Army installations. Providers who receive the PE workshop in each Army installation will be randomly assigned to either Standard PE training or Extended PE training. We hypothesize that compared to Standard training, Extended PE training will lead to: 1) Greater frequency of PE delivery; 2) Superior outcome; and 3) Higher provider self-efficacy and positive attitudes towards PE.

BODY

The following report on study activities has been divided by study site (Ft. Carson, Ft. Bliss, and Ft. Campbell) and overall study progress, respectively. These tasks have been completed during the third year of the project (September 29, 2014 – September 29, 2015):

Ft. Carson

The study was funded in September 2013. The Ft. Carson site-specific protocol was approved by the Madigan Army Medical Center IRB in April 2014 and was subsequently forwarded to HRPO

for approval. HRPO granted its approval of the study in September 2014. Immediately after receiving HRPO approval, recruitment for provider-participants at Ft. Carson was initiated. From September to November 2014, 25 provider-participants were enrolled in the study. Two 4-day PE workshops offering instruction in Prolonged Exposure therapy (PE) for PTSD were scheduled for early January 2015. The time gap between September to January represents the time required to recruit providers and to allow them sufficient time to change their clinical templates so that they could begin patient recruitment immediately after the workshop. In December 2014, two weeks prior to the January workshops, Extended condition providers were contacted by their consultants to initiate consultation and receive guidance on how to select two PE training cases.

The PE training workshops took place on January 6-9 and 12-15, 2015. Enrolled study providers were trained in administering PE by an expert trainer, and were further briefed on study procedures by the Penn research team. Recruitment for patient-participants at Ft. Carson began in January 2015 immediately after the workshops, with Standard condition providers referring patients to the BOAs for assessment and determination of whether the patient met criteria for entering the study. To date, 29 patient-participants have been enrolled at Ft. Carson. Also immediately following the workshops, Extended condition providers began receiving weekly supervision on their two training cases.

The first MAMC IRB continuing review was due on April 8, 2015. The Ft. Carson site-specific protocol, consent forms, and supporting documentation were submitted on February 20, 2015 for review, and were approved on March 18, 2015.

Ft. Carson experienced some staff attrition in Spring 2015. Dr. Jeremy Francis resigned from the position of On-Site PI to Site Sub-Investigator in April 2015. Heather Campbell, Ph.D. was appointed to take over the role, and began her new position on May 8, 2015. Sally Curtis resigned from the position of Research Assistant at Ft. Carson in May 2015. A new RA, Adam Ward, was hired to replace Ms. Curtis, and began on June 16, 2015.

A renewal of the Data Sharing Agreement allowing study staff to use data from the Behavioral Health Data Platform was submitted to LTC Millard Brown (owner of the BHDP) on August 27, 2015 and is pending approval.

Site-Specific Challenges

Provider and patient-participant attrition proved to be a major challenge at this site. Of the 25 providers originally recruited, 14 withdrew from the study due to schedule changes, relocation, or changes to caseload that made study participation difficult. Initial patient referrals were also slow, due largely to providers' misconceptions of the study as a "PE study," and therefore their reluctance to refer otherwise eligible patients whom they deemed inappropriate for PE. The study team implemented various efforts to re-educate providers regarding the goal of the study, including holding individual provider meetings, presenting the study to the Behavioral Health Department on base, and revising recruitment materials. These efforts have met with moderate success, with an increase in percentage of slots filled from 39% to 52%. Efforts continue to increase the number of patients referred to the study by participating providers.

Ft. Bliss

Following MAMC IRB approval of the Ft. Carson site in April 2014, the study team immediately began preparing the Ft. Bliss site-specific protocol, consent forms, and all supporting documents for submission to the MAMC IRB. In order to facilitate the MAMC IRB's review of the Ft. Bliss site, Dr. Stacey Young-McCaughan and Deanne Hargita of UTHSCSA worked with the Penn team and the site teams at Ft. Carson and Ft. Bliss to ensure that the Ft. Bliss documents were consistent with the Penn Core protocol and Ft. Carson site-specific protocol. The Ft. Bliss documents were also revised to incorporate several major modifications made to the Ft. Carson protocol upon request by HRPO. Following feedback from all members of the study team, the revised Ft. Bliss site documents were submitted to Madigan for review in August 2015. The William Beaumont Army Medical Center IRB conducted an administrative and legal review of the package, and forwarded its acknowledgement to the MAMC IRB on August 28. Madigan conducted its administrative regulatory review of the Ft. Bliss package in October 2014, and forwarded a request for additional information to the On-Site PI, Dr. Brenda Hanson. Dr. Hanson returned her response on October 24. The Ft. Bliss package underwent final

expedited review beginning in December 2014. The MAMC IRB contacted the study team with a request for additional materials in mid-January 2015, which the study team responded to promptly. The MAMC IRB approved the Ft. Bliss site package on January 27, 2015, and minutes from the MAMC IRB's review meeting were forwarded to Ft. Bliss site leadership for final approval. The first MAMC IRB continuing review for Ft. Bliss was submitted for review on February 20, 2015, soon after initial study approval was received by Ft. Bliss (on January 27). The Ft. Bliss site-specific protocol and supporting documents were re-approved by the MAMC IRB on April 2, 2015.

The William Beaumont Army Medical Center DCI issued a start letter to commence recruitment of provider-participants on March 19, 2015, with plans to issue a separate start letter for patient-participant recruitment. Thus, IRB activities for final approval to begin provider recruitment began in August 2014 and were completed in March 2015. Provider-participant recruitment was initiated immediately following receipt of the DCI's start letter. From March to April 2015, 13 providers were consented to the study at Ft. Bliss.

Two 4-day workshops offering instruction to study providers in Prolonged Exposure therapy (PE) for PTSD were scheduled for June 2015. The workshops were scheduled 3 months from the start of provider recruitment to allow providers the necessary time to change their clinical templates, thus ensuring that providers could attend the workshop and begin referring patients immediately thereafter. In preparation for the workshops, Extended condition providers were assigned to expert PE consultants at Penn, and were contacted by their consultants two weeks prior to the workshops to initiate consultation and receive guidance on selecting two PE training cases. The PE workshops were held at Ft. Bliss on June 2-5 and 8-11, 2015. Enrolled study providers were trained in administering PE by an expert trainer, and were further briefed on study procedures by the Penn research team. Directly following the workshops, PE consultants at Penn began providing weekly case supervision to study providers.

The WBAMC DCI issued a start letter authorizing patient-participant recruitment on May 4, 2015. Patient-participant recruitment at Ft. Bliss began in June 2015, upon conclusion of the workshops. To date, 11 patients have been enrolled to the study at Ft. Bliss, with 8 eligible

patients currently in therapy with study providers. Patient assessments were temporarily put on hold when Behavioral Outcomes Assessors Lesley Buck and Jan Bestwick left the Ft. Bliss team on June 26, 2015. The BOA position was immediately posted to hiring websites and local advertisements, and several candidates were identified. An initial part-time offer was made to Loreli Leos, LPC in July, and after renegotiation was accepted in August. Ms. Leos' official start date was September 2, 2015. Dr. Nicole Peak, BOA at Ft. Carson, visited Ft. Bliss on September 2-3, 2015 to train Ms. Loreli Leos in performing patient assessments and to conduct a second assessment for patients. Ms. Leos is completing a training course through the National Center for PTSD in administering the CAPS. Hiring efforts for the second BOA position have continued.

In addition to the BOA positions, Ft. Bliss experienced turnover in other staff positions throughout the year. Dr. Martin Ancona withdrew from the position of Provider-Therapist at Ft. Bliss in late September 2014, and hiring efforts for the position resumed. To facilitate hiring, the Geneva Foundation requested and received permission from local site leadership at Ft. Bliss to widen the search for Provider-Therapists to include Licensed Clinical Social Workers and Licensed Marriage/Family Therapists, in addition to Licensed Clinical Psychologists. Meredith Wolrich, LCSW was hired as a Provider-Therapist at Ft. Bliss and commenced her role on January 9, 2015. Rachell Jones, Research Assistant at Ft. Bliss, resigned from the position on January 8, 2015. A new RA, Julie Blow, Ph.D. was trained to take over administrative duties, and officially started on February 23, 2015. Ms. Wolrich left the position of Provider-Therapist on July 2, 2015. Graciela Pinon, LMFT was subsequently hired as a Provider-Therapist, and is slated to start in late September.

Site-Specific Challenges

Delays in receiving the MAMC IRB's final approval and the WBAMC DCI's start letter led to subsequent delays in initiation of provider-participant recruitment at Ft. Bliss. The site has also experienced an unprecedented rate of staff turnover, with four out of five Geneva-hired staff members leaving their posts in less than one year. In particular, the departure of two BOAs in June 2015 caused further delays in patient referral and recruitment. Dr. Nicole Peak of Ft. Carson traveled to Ft. Bliss on September 2, 2015 to provide temporary coverage for patient assessments. Scheduling of first assessments has since been resumed, with plans for BOAs from

Ft. Carson or Ft. Campbell to provide temporary coverage until Loreli Leos has successfully completed CAPS training.

Ft. Campbell

Following submission of the Ft. Bliss site-specific documents to the MAMC IRB for review in August 2014, the site-specific protocol and supporting documents for the Ft. Campbell site were sent to the MAMC IRB for review on September 2, 2014. The Ft. Campbell package was pre-reviewed by the DDEAMC IRB in mid-October 2014, and was subsequently forwarded to the MAMC IRB for final review. MAMC IRB conducted their pre-review on October 20 and returned the package to the study team with an additional request for materials; the study team resubmitted the package on November 7. Madigan made an additional request on December 5 for recruitment materials to be approved by Ft. Campbell site leadership. The study team contacted leadership immediately for approval, received the approved recruitment materials on December 15, and subsequently forwarded the requested materials to Madigan. The MAMC IRB's final expedited review of the package was delayed due to its review of the other sites' continuing review packages (submitted February 20). In early March, Madigan stated its intent to not release Ft. Campbell's approval until after the other sites' continuing reviews were approved. MAMC IRB approval of the Ft. Campbell package was received on April 15, 2015, and the minutes from the MAMC IRB review meeting were forwarded to local leadership at Ft. Campbell for their approval. A start letter from site leadership was received on June 1, 2015. Recruitment for provider-participants at Ft. Campbell began immediately after, and providers and site leadership were contacted to specify available dates for conducting the workshop. As with the other sites, at least three months between recruitment and workshop were required to ensure that providers' templates could be changed. Based on providers' stated availabilities and the base's template requirements, two separate workshops were scheduled, one in September 2015 and a second in December 2015.

The last provider-participant for the current round of recruitment was enrolled in early September, bringing the total number of enrolled provider-participants to 17. Expert PE consultants at Penn have been assigned consultees from Ft. Campbell, and have begun scheduling weekly consultation calls in preparation for the September 28 workshop. A 4-day

professional workshop to train enrolled study providers in Prolonged Exposure therapy (PE) for PTSD will take place at Ft. Campbell on September 28-October 1, 2015. A second workshop has been scheduled at Ft. Campbell for December 7-10, 2015.

Staff attrition was experienced on two separate occasions this year. Ivett Lillard stepped down from the role of On-Site PI at Ft. Campbell in February 2015. CPT Valerie Scott was appointed to take over the position, and became active in the role on February 20, 2015. Kristen Butcher resigned from the position of Research Assistant at Ft. Campbell in June 2015. Hiring efforts were initiated immediately, and a new RA, Elizabeth Eversole, was hired and started in August 2015.

Site-Specific Challenges

The Ft. Campbell site experienced considerable delays in receiving IRB approval: IRB activities commenced in September 2014 and local site leadership approval was not granted until June 2015, resulting in a months-long delay of provider-participant recruitment. Following IRB approval, no additional site-specific challenges have been encountered.

Overall Study Progress

Drs. Foa, McLean, and Zandberg have continued to hold one-hour weekly telephone conference calls with Drs. Peterson and Young-McCaughan at UTHSCSA, Miranda Bethay and Yaa Arhin at the Geneva Foundation, and the site study teams. Conference calls have focused on obtaining IRB approval and responding to IRB concerns, hiring study staff, forming recruitment strategies and reporting on recruitment efforts, planning training workshops and site visits, and addressing any study-related concerns at the local military sites. Weekly research meetings have also been held by PI Dr. Foa, Dr. McLean, Dr. Zandberg, and Jody Zhong at the University of Pennsylvania to discuss ongoing coordination of the study.

A prototype of the study database was created by contractors at UTHSCSA, and forwarded to the Penn team for review in October 2014. Following revisions made based on the Penn team's feedback, the prototype was then sent to each of the local military sites for beta testing. A 2-day training session was held at Ft. Carson on December 4-5 to train study staff on using the new

database. Ray Aguilar, Antoinette Brundige, and Dr. Stacey Young-McCaughan of UTHSCSA presented the study database to staff members from each site (Mrudala Raparla from Ft. Bliss, Jennifer Deluzio from Ft. Campbell, and Lori-Ann Landry and Sally Curtis at Ft. Carson) and answered questions from the study staff. Following the database training, study staff at each site spent two months troubleshooting the database and forwarding suggested revisions to Ray Aguilar.

Dr. Foa visited Ft. Campbell on November 17th, 2014. While there, Dr. Foa met with site leadership, including COL Lang (Chief of Behavioral Health), to present the study and gain local support. Dr. Alan Peterson, Director of the STRONG STAR Consortium, Dr. Ron Hoover of the MOMRP, and Inna Williams, Science Officer at CDMRP, were also present at Ft. Campbell to discuss study progress and challenges.

Immediately following the start of patient-participant recruitment at Ft. Carson in mid-January, a weekly BOA reliability call was initiated by an expert clinician at Penn (Sandra Capaldi, Psy.D.). The BOAs and Dr. Capaldi have held weekly calls since then to provide the BOAs with feedback on assessments and to discuss assessment-related questions.

The first MAMC IRB continuing review of the Penn Core study protocol was due on April 8, 2015. The Penn Core study protocol and supporting documents were submitted to the MAMC IRB for review on February 20, 2015, and were approved on March 18, 2015.

The second Penn IRB continuing review was due on August 18, 2015. Continuing review documents for the Penn site, in addition to supplementary reports from the Ft. Carson, Ft. Bliss, and Ft. Campbell sites, were submitted to the Penn IRB on June 18, 2015. Penn IRB re-approval of the study was received on August 5, 2015.

Dr. Zandberg visited Ft. Carson on July 23, 2015. Dr. Zandberg made a presentation to the Department of Behavioral Health to facilitate participant recruitment, met with study staff, and met with current provider participants to reinforce participation and trouble-shoot barriers to patient recruitment.

Problem Areas

Due to the delays in MAMC IRB approval of each local military site, participant recruitment for the study did not begin until September of 2014 at Ft. Carson, and at Ft. Bliss and Ft. Campbell until late March and May of 2015, respectively. Even after provider recruitment began, all three sites experienced challenges in recruiting provider-participants, due to an apparent scarcity of providers with caseloads that render them eligible for study participation (e.g. an anticipated caseload consisting of at least 20% patients with posttraumatic symptoms). Many providers do not see patients for ongoing treatment of PTSD or other difficulties, but see patients for a single consultation session on specific issues, such as separation from the Army. Still other providers conduct couples or family therapy and do not provide individual therapy. This has reduced the pool of available providers that meet the criteria for participating in the study. Even among providers who meet criteria for participating in the study, retention of participants has remained difficult, with higher than expected attrition among provider-participants at Ft. Carson (56%). Finally, recruitment for patient-participants has been slower than anticipated (only 44% of available slots for patient-participants had been filled as of three weeks ago, and 52% have been filled as of last week).

Since the first workshops at Ft. Carson in January 2015, the team worked to initiate strategies to promote provider retention and participation, and to facilitate patient referrals (e.g. clarifying providers' understanding of patient inclusion criteria, scheduling meetings with providers to troubleshoot recruitment challenges). In addition, recruitment materials were modified and the inclusion criteria for the study were changed to improve recruitment. Namely, the provider inclusion criteria were adjusted from "current caseload with at least 20% patients with PTS symptoms," to "anticipated caseload with at least 20% patients with PTS symptoms"; in addition, the patient inclusion were also modified, from "diagnosis of PTSD" to "significant PTS symptoms." Each of these changes was developed in direct response to the challenges faced at Ft. Carson, but these changes required IRB approval, resulting in unfortunate delays before they could be implemented across the sites.

However, once these strategies were implemented, evidence suggests that they have facilitated participant recruitment. Using the revised protocol and materials, Ft. Bliss (as the second site to begin recruitment) has experienced greater success: 70% of provider-participants have been retained, and 76% of available study slots for patient-participants have been filled.

Staff turnover at each site has been high, creating a need for ongoing hiring efforts across a variety of positions. Currently, all positions are filled with the exception of one BOA position at Ft. Bliss, and the Provider-Therapist position at Ft. Carson.

KEY RESEARCH ACCOMPLISHMENTS

- Provider participant recruitment initiated at all three sites.
- Training workshops held for study providers at Ft. Carson and Ft. Bliss
- Patient recruitment initiated at Ft. Carson and Ft. Bliss
- Expert consultation ongoing for providers in Extended study condition
- Hired key study staff, including BOAs, RAs, and Provider-Therapists, for each site.

REPORTABLE OUTCOMES

To date, there are no reportable outcomes.

CONCLUSION

Accessibility of effective PTSD treatment is an extremely relevant issue for the military and for our national public health in general. The proposed research will help identify the most effective PE training model while ensuring sustainability of implementation and maintenance of treatment quality and adherence. This study constitutes a key step towards the ultimate goal of increased access to evidence-based treatment among soldiers suffering from PTSD and related problems. The results will inform EBT dissemination efforts in the military as well as the public sector.

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APPENDICES

Appendix A: Madigan Army Medical Center IRB Local Site Approval & Start Letter for Ft. Bliss

Appendix B: Madigan Army Medical Center IRB Local Site Approval & Start Letter for Ft. Campbell

Appendix A: MAMC IRB Approval of Ft. Bliss

DEPARTMENT OF THE ARMY
WILLIAM BEAUMONT ARMY MEDICAL CENTER
5005 N PIEDRAS STREET
EL PASO TX 79920-5001

REPLY TO
ATTENTION OF

MCHM-DCI

DATE: 5 March 2015

MEMORANDUM THRU

COL Mark P. Pallis, DO, MC, Deputy Commander for Clinical Services, WBAMC CRP
COL Michael S. Heimall, Commander, WBAMC

FOR Brenda S. Hanson, PhD, Principal Investigator

SUBJECT: Initial Approval of Research Protocol / Local Site Start Letter

STUDY TITLE: Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?
REFERENCE: #14/31
IRBNet: #395963-1
SUBMISSION TYPE: New Submission
ACTION: APPROVED
APPROVAL DATE: 27 January 2015
EXPIRATION DATE: 8 April 2015
REVIEW TYPE: Full Board

1. Congratulations! The Madigan Army Medical Center (MAMC) Institutional Review Board (IRB) has approved your protocol. You are approved to begin your study as specified in the Start Letter issued by the MAMC IRB on 27 January 2015.

2. You are approved to enroll not more than 40 mental health providers and 170 patients seeking treatment with PTSD symptoms who are assigned to the mental health providers participating in the study at William Beaumont Army Medical Center (WBAMC).

3. In accordance with WBAMC policies, you are required to secure the appropriate data sharing agreements (DSA) prior to initiation of use of those data sources in your study. According to the IRB-approved protocol documents, the Behavioral Health Data Platform (BHDP) will be used to identify and recruit patients to participate in this study. **You are not permitted to collect data for research purposes from BHDP until the required DSA is fully executed; therefore you cannot recruit patients until the DSA is secured.**

4. Upon receipt of this signed letter at your New Protocol Briefing, you may begin recruiting and enrolling providers as specified in item 3 above. The New Protocol Briefing is required for all new protocols.

5. **Please be reminded that this Start Letter is limited to the enrolling providers.** Study activities involving access to and use of data from the BHDP database for research purposes at this time shall not start until the DSA is fully executed.

6. A copy of this letter is posted on IRBNet for access as needed. The signed start letter for the enrolling of subjects and providers will be issued to you at your New Protocol Briefing, which is required for all new protocols. To access this letter in IRBNet, go under Project Administration, select the Reviews tab and on the next page scroll thru Board Documents. Once the pending DSA is executed, a new start letter covering the full study activity will be issued.

7. POC for this IRB action is the Department of Clinical Investigation, William Beaumont Army Medical Center at (915) 742-6075.

3/5/2015

X Michael P. Abel, MD

LTC/P, MC
Chief, Department of Clinical Investigation
Signed by: ABEL.MICHAEL.PHILIP.1088510590

Appendix B: MAMC IRB Approval of Ft. Campbell

DEPARTMENT OF THE ARMY
MADIGAN army MEDICAL CENTER
9040 JACKSON AVENUE
TACOMA, WA 98431-1100

REPLY TO
ATTENTION OF

MCHJ-CLI

DATE:	16 April 2015
TO:	CPT Valerie D. Scott, Psy.D, Blanchfield Army Community Hospital, Fort Campbell, KY 42223
FROM:	Chairman, Institutional Review Board
SUBJECT:	Initial Approval of Research Protocol
STUDY TITLE:	Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?
REFERENCE	#215045
IRBNet	#395965-1
SUBMISSION TYPE:	Multisite New Project for Local Site - BACH
ACTION:	APPROVED
APPROVAL DATE:	16 April 2015
EXPIRATION DATE:	07 April 2016
REVIEW TYPE:	Full IRB Review

1. Congratulations! Your BACH Site Specific Addendum (version date 13 February 2015), including all accompanying study documents was found to have scientific merit and IAW 32 CFR 219.110(b)(1), categories 6 & 7, is approved as a minimal risk human use protocol by expedited procedures on 16 April 2015 through expiration date 07 April 2016 (synchronized with the Core Protocol).

2. You are approved to enroll not more than 40 mental health providers and 170 patients seeking treatment with PTSD symptoms who are assigned to the mental health providers participating in the study at Blanchfield Army Community Hospital (BACH).

3. Two (2) consent forms have been approved for use with this protocol; One (1) for PATIENTS with embedded HIPAA and one (1) for PROVIDERS without HIPAA (approved /stamped date of 16 April 2015; expiration date of 07 April 2016) in accordance with Federal regulations at 32 CFR 219.116, 21 CFR 50.20 and 50.25, AR 40-7, and 45 CFR 164.512. **The approved stamped consent forms must be duplicated and used for enrolling subjects.**

4. A Partial Waiver of HIPAA Authorization (dated 16 April 2015) is also approved IAW DOD 6025.18-R C7.9. and HIPAA (45 CFR 164.512(i)) because the use of minimal personal health information (PHI) is being used to screen subjects prior to obtaining consent which involves no more than minimal risk to the privacy of individuals based upon the presence of each of the following: identifiers will be maintained via hard copy files in a locked filing cabinet in a locked office and electronically on password protected CAC enabled government computers only accessible by the PI and Study Staff; the PI will destroy identifiers at the earliest opportunity (upon closure of the study); the PI has provided written assurance

SUBJECT: Initial approval of Research Protocol

that the PHI will not be reused or disclosed, except as required by law, for authorized oversight, or for other research for which use/disclosure would be permitted under the Privacy Rule.

5. This approval has been synchronized with the Core Protocol expiration date and this approval is valid through 28 April 2015. As part of your continuing review and re-approval, and in order to keep your research ongoing, you are required to submit a continuing review report in March 2016. Failure to do so may result in a lapse of approval and a halt to your research project.

6. A copy of the approved BACH Site Specific Addendum will be posted on IRBNet for your access; 2 stamped original consent forms will be forwarded to you directly for your records.

7. Funding for this study is from the U. S. Army Medical Research and Materiel Command (USAMRMC) Military Operational Medicine Research Program (MOMRP RAD 3) through the Geneva Foundation under subcontract from the University of Pennsylvania.

8. Please note that as the Principal Investigator (PI) for this study, Federal, DoD, Army and Madigan Army Medical Center regulations and policies require you to submit the following in a timely fashion to the Institutional Review Board, if applicable:

(a) amendments delineating any changes to the protocol
(b) PI change
(c) notification of serious or unexpected adverse effects and unanticipated problems involving risks to subjects and others within 24 hours
(d) publication clearance, travel orders, and funding requests
(e) deviation reports
(f) continuing review reports.

9. As the Principal Investigator, you have also acknowledged that you will conduct this research in accordance with all local and Federal research regulatory requirements. If at any time you feel that you cannot perform this research as required, you must contact this office immediately.

10. No Research Monitor has been assigned this protocol as this protocol was determined to be minimal risk.

11. You are reminded that a publication clearance is required for all written materials (i.e. manuscript, presentation, or abstract) being submitted for publication/presentation.

12. Federal regulations at 21 CFR 56.109(e) affords you the opportunity to address the Board in person or in writing regarding its actions. Please contact the Department of Clinical Investigation, at 253-968-0149 for additional information, or if you have any questions regarding the Board's actions.

DAVID P. HARPER, MD
LTC, MC
Chairman, Institutional Review Board